

SEP 21 2001

K012008



510(k) SUMMARY

STS Compression Sleeves

Company Huntleigh Healthcare Inc
40 Christopher Way
Eatontown
New Jersey

Contact Audrey Witko
Phone 732 578 9898
Fax 732 460 5809

Summary Preparation Date 19 June 2001

Trade Name STS20 Knee Length Size
STS30 Thigh Length Medium Size
STS40 Thigh Length Large Size

Common Name Gradient, Sequential Compression Sleeves

Classification Name Sleeve, Limb, Compression (JOW)

Predicate Device Kendall SCD Therapeutic System K890938

Device Description

The STS range of sleeves, are three chamber graduated, sequential compression sleeves, to be used in conjunction with the Huntleigh AC600 Flowtron Universal pump (K010744).

Intended Use

The STS system is designed to help prevent Deep Vein Thrombosis (DVT), by increasing venous blood flow.

Summary of Technological Characteristics

The STS range of compression sleeves consist of two sheets of PVC laminate materials welded together to form three chambers. The size and shape of these chambers are similar to the predicate device, as is the method of fitting to the patient's limb.

On the predicate device, separate tubes individually inflate the three chambers. On the proposed device, a single tube into the lower chamber inflates the complete sleeve. Sequential, graduated and gradient inflation of the middle and upper chambers is achieved by a series of bleed channels between chambers and bleed orifices to atmosphere.

On the predicate device, the material in contact with the patient's skin is non-woven fibre. The STS has a layer of polyester foam against the patient's skin, identical in composition to other approved Huntleigh sleeves.

The systems have similar fault alarms, i.e. low pressure, blocked/kinked tubes, and system faults.

Determination of Substantial Equivalence

The determination of Substantial Equivalence is based on non-clinical, inflation performance testing. The sleeves are tested by fitting to a subject's limbs and the pressure/time cycle results compared.

Equivalence Testing Results

The sleeves are made from similar materials and compress a similar area of the patient's limb. The inflation sequence and pressures in each chamber are similar.

Therefore, we propose that the clinical treatment that the patient receives will be equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2001

Ms. Audrey Witko
Huntleigh Healthcare, Inc.
40 Christopher Way
Eatontown, NJ 07724

Re: K012008

Trade Name: STS Range Models STS20, STS30, and STS40

Regulation Number: 21 CFR 870.5800

Regulation Name: Sleeve, Limb, Compression

Regulatory Class: Class II (two)

Product Code: JOW

Dated: June 27, 2001

Received: June 27, 2001

Dear Ms. Witko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

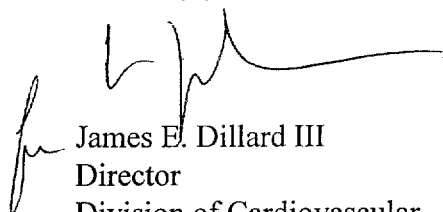
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name.

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement
STS Compression Sleeves

Ver/3 – 4/24/96

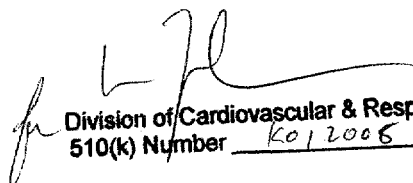
Applicant: Huntleigh Healthcare Inc.

510(k) Number (if known): ~~Not known at present~~ K012008

Device Name: STS

Indications For Use:

The STS system is designed to help prevent Deep Vein Thrombosis (DVT), by increasing venous blood flow.


Division of Cardiovascular & Respiratory Devices
510(k) Number K012008

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)